

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

JOHN M. FLACK ET AL.

Serial No.: 10/036,202

Filed: December 27, 2001

Group Art Unit: 3626

Examiner: Robert D. Rines

For: COMPUTER-IMPLEMENTED METHOD AND SYSTEM
FOR MANAGING PATIENT HEALTHCARE
AND EVALUATING PATIENT KIDNEY FUNCTION

Attorney Docket No.: MTS 0102 PUS

APPEAL BRIEF

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Sir:

This Appeal Brief is submitted in support of Applicants' appeal of the final rejection of claims 1-19 made in the Office Action mailed February 11, 2008.

I. REAL PARTY IN INTEREST

The real parties in interest are the individual Applicants, John M. Flack, M.D. and Lowell A. Hedquist.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-19 are pending. Claims 1-19 stand rejected and are the subject of this Appeal.

IV. STATUS OF AMENDMENTS

None.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 provides a patient healthcare management system having a capability to evaluate patient kidney function. The system is configured to receive input defining a patient's medical record including the patient's demographic information, medical condition and diagnosis, Specification, p. 12, l. 24 - p. 14, l. 28, calculate the patient's estimated glomerular filtration rate based on the patient's medical record, Specification, p. 22, ll. 11-24, and output at least one medical treatment recommendation wherein the recommendation is based on the patient's medical record and estimated glomerular filtration rate, Specification, Table 2, pp. 25-28. The system is further configured to calculate and output at least one treatment goal for the patient. Specification, pp. 23, ll. 1-16.

Claim 10 provides a computer-implemented patient healthcare management method involving the evaluation of patient kidney function. The method includes defining a patient's medical record including the patient's demographic information, medical condition and diagnosis, Specification, p. 12, l. 24 - p. 14, l. 28, calculating the patient's estimated glomerular filtration rate based on the patient's medical record, Specification, p. 22, ll. 11-24, and automatically generating at least one medical treatment recommendation based on the patient's medical record and estimated glomerular filtration rate, Specification, Table 2, pp. 25-28. The method also includes calculating at least one treatment goal for the patient. Specification, pp. 23, ll. 1-16.

Claim 19 provides a computer-based system for interactively managing patient healthcare and evaluating patient kidney function. The system includes a means for defining a patient's medical record, Specification, p. 12, l. 24 - p. 14, l. 28, a means for establishing the patient's estimated glomerular filtration rate based on the patient's medical record, Specification, p. 22, ll. 11-24, and a means for generating at least one patient treatment recommendation based on the patient's medical record and estimated glomerular filtration rate, Specification, Table 2,

pp. 25-28. The system also includes a means for calculating at least one treatment goal for the patient. Specification, pp. 23, ll. 1-16.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pub. No. 2004/0260666 (Pestotnik) and U.S. Pub. No. 2003/0019115 (Tannenbaum).

VII. ARGUMENT

A. Claims 1-19 are patentable under 35 U.S.C. 103(a) over Pestotnik and Tannenbaum

With regard to claim 1, Pestotnik does not disclose a system configured to calculate and output at least one treatment goal for the patient. The Examiner cites Pestotnik paragraphs 94, 150 and 151 for this limitation:

[0094] In one setting, a clinician may request that progress note module 236 summarize the decision-supported patient data generated by inference module 232. The summarized decision-supported patient data contains the pertinent information related to the medical condition of the patient in an easily viewed display. For example, if the patient has diabetes, progress note module 236 will generate a decision-supported progress note that summarizes the pertinent medical parameters associated with the patient's diabetes, such as the most recently acquired heart rate, blood pressure, blood sugar level, and the like, while providing warnings or alerts to the clinician. Similarly, when a therapeutic regimen is suggested, progress note module 236 summarizes decision-supported patient data includes drug name and type, dose, route, interval and duration of therapy specific to the patient and the drug, patient demographics, and the like, while providing warnings or alerts to the clinician.

[0150] Following obtaining the etiology, decision-support module 210 gathers any susceptibilities and any mitigating factors. In this particular example, no susceptibilities are necessary. In contrast, however, a number of mitigating factors may be displayed or presented to the clinician. Such mitigating factors may include,

but are not limited to pregnancy or post-partum state, renal transplant or other immunosuppression, use of diaphragm prior to onset, recurrence, early relapse of initial treatment failure, diabetes, neurogenic bladder, recent urologic surgery/instrumentation, obstruction or abnormal urological anatomy, duration of symptoms for longer than seven (7) days, age less than three (3) years, and the like. Each mitigating factor may include a rule stored in knowledge module 226 that may be used to guide the decision-support process of the present invention.

[0151] Upon completing the above analysis, decision-support module 210 generates an updated decision-supported patient data and decision-supported progress note with a ranked list of recommendations, as represented by blocks 376 and 378. In this example, decision-support module 210 also identifies whether the existing medical care is successful in treating the urinary tract infection and generates a recommendation based upon the current success of the regime.

Pestotnik, [0094], [0150]-[0151] (emphasis added).

Summarizing patient data, gathering susceptibles and mitigating factors, and generating updated patient data, progress notes and recommendations simply does not disclose calculating at least one treatment goal for the patient.

With regard to claim 1, the Examiner asserts that

It would have been obvious to one of ordinary skill . . . to have combined the teachings of Pestotnik et al. with those of Tannenbaum. Such a combined system and method would have referenced an expert knowledge base to evaluate entered the patient data to identify known or unknown medical conditions and provide decision-supported data to a physician including guidance as to the potential medical conditions of the patient and to aid the clinician in making informed decisions related to patient medical care (Pestotnik et al.; paragraphs [0011] [0017] [0018] [0085]). Further, such a system-enabled method, when specifically configured to assist a physician in diagnosing and treating renal diseases, would have included in the expert knowledge base, calculators/equations for providing information on well-known clinical indicators such as Glomerular Filtration Rate (GFR) as

determined by well-known equations such as the Cockcroft-Gault equation and commonly employed variants thereof (Tannenbaum; Abstract and paragraphs [0025]-[0036] and [0047]).

Office Action, February 11, 2008, p. 4.

Pestotnik, however, is only configured to use "rules" to generate medical diagnoses and patient care recommendations:

Illustrative rules and statements for the diagnosis and treatment of Pneumonia are represented in Tables 1-5 of FIGS. 6-10. As illustrated, Table 1 contains a plurality of rules that may be used by inference module 230 to generate the decision-supported patient data and the decision-supported progress note, thereby providing the clinician with a recommended medical treatment for a medical condition. Tables 2-5 (FIGS. 7-10) contain a number of rules specific to certain information collected by system 200; specifically, optionally sequentially activated rules associated with the analysis of mitigating factors, susceptibilities, and duration of treatment. One skilled in the art may appreciate that various other rules may be appropriate to generate a recommendation for treatment of Pneumonia.

Pestotnik, [0142] (emphasis added).

These rules are a series of if-then statements. As an example, Rule #1 of Table 1 states that

If ventilator or non-ventilator HAP and organism unknown and interval from admission > 5 days and (severity is severe or recent prior antibiotics) and Legionella cases identified, then (ceftazidime + ciprofloxacin), (aztreonam + ciprofloxacin (admitted through intravenous)(IV)), piperacillin/tazobactam + macrolide IV

Pestotnik, Figure 6A.

As another example, Rule #3 of Table 1 states that

If ventilator or non-ventilator HAP and organism unknown and interval from admission > 5 days, then piperacillin/tazobactam, ceftazidime, ciprofloxacin IV.

Pestotnik, Figure 6A.

The Examiner asserts that "Pestotnik does not exclude calculations performed using well known equations" Office Action, February 11, 2008, p. 10. The if-then statements of Pestotnik, however, simply cannot be used to calculate an estimated glomerular filtration rate as claimed. As such, there is no way for Pestotnik to calculate an estimated glomerular filtration rate without changing its principle of operation. See MPEP 2143.01(VI). Pestotnik does not have the capability of being combined with a hand held calculator such as that disclosed in Tannenbaum. One of ordinary skill in the art, therefore, would not have had reason to combine the teachings of Pestotnik and Tannenbaum. Accordingly, the Examiner has not established a *prima facie* case of obviousness for claim 1.

Claims 10 and 19 are patentable for the reasons claim 1 is patentable.

Claims 2-9 and 11-18 are patentable because they depend from one of the independent claims.

35 U.S.C. 112 provides that

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. 112, 6th paragraph.

With regard to claim 19, Tannenbaum does not teach the means, as disclosed by the Applicants, for establishing the patient's estimated glomerular filtration rate based on the patient's medical record. The Examiner asserts that "Tannenbaum discloses a means for calculating the patient's estimated glomerular filtration rate based on the patient's medical record (Tannenbaum; paragraphs [0025]-[0036] [0047])." Office Action, February 11, 2008, p. 8. The Applicants, however, disclose that

Figure 17 illustrates an example GUI 234 containing an "Estimated Glomerular Filtration Rate" (EGFR) calculator in accordance with the preferred embodiment of the present invention. The EGFR calculator extracts patient information 236 previously entered which is necessary to calculate (i.e., estimate) the patient's glomerular filtration rate. In accord with a preferred embodiment, the patient's current data is automatically input into the appropriate data entry fields in an editable format. Default patient information can be edited for purposes of estimating the patient's glomerular filtration rate without changing the patient's information of record generated via the various patient encounter modules.

In accordance with a preferred embodiment of the present invention, the patient's glomerular filtration rate is estimated according to Equations 1 and 2:

$$\text{EGFR} = \left[\frac{((140 - \text{AGE}) \times \text{WEIGHT}(\text{kg}))}{72 \times \text{SCR}} \right] \times \left[\frac{1.73}{\text{BSA}} \right] \quad \text{Eqn. 1}$$

$$\text{BSA} = 0.007184 \times [\text{HEIGHT}(\text{cm})^{0.725}] \times [\text{WEIGHT}(\text{kg})^{0.425}] \quad \text{Eqn. 2}$$

For female patients, the EGFR is multiplied by 0.85 to correct for gender differences in muscle mass and average rate of creatinine synthesis.

Application, p. 22, ll. 11-26 (emphasis added).

In contrast, Tannenbaum provides a slide ruler and calculator "for calculating the Glomerular Filtration Rate (GFR) of a patient" Tannenbaum, Abstract. Tannenbaum's calculations,

however, are not based on the patient's medical record: Tannenbaum lacks the claimed patient's medical record. See, Tannenbaum.

With regard to claim 19, Tannenbaum does not teach the means, as disclosed by the Applicants, for calculating at least one treatment goal for the patient. The Examiner attempts to find this limitation in paragraphs [0094], [0150] and [0151] of Pestotnik. See, Office Action, February 11, 2008, p. 7. The Applicants, however, disclose that

Figure 18 illustrates an example GUI 238 containing an "LDL Cholesterol Goal" calculator in accordance with the present invention. The cholesterol goal calculator extracts patient information 240 previously entered which is necessary to calculate (i.e., estimate) the patient's goal LDL cholesterol level. The patient's current data is automatically input into the appropriate data entry fields in an editable format. Default patient information can be edited for purposes of estimating the patient's goal LDL cholesterol level without changing the patient's information of record generated via the various patient encounter modules.

In accordance with a preferred embodiment of the present invention, the combined consideration of whether the patient has CHD or diabetes and the member of coronary heart disease risk factors.

Notably, a variety of patient treatment goals may be calculated and/or automatically generated based on patient records in accord with the present invention. Other patient treatment goals envisioned include, but are not limited to, target blood pressure (as illustrated and described in Figure 8), target lipid levels and target hemoglobin A1C levels.

Application, p. 23, ll. 2-16.

As discussed above, Pestotnik does not calculate at least one treatment goal for the patient, *a fortiori*, calculate at least one treatment goal for the patient in the manner disclosed by the Applicants.

Please charge any additional fee or credit any overpayment in connection with this filing to Deposit Account No. 02-3978.

Respectfully submitted,

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Enclosure - Appendices

VIII. CLAIMS APPENDIX

1. A patient healthcare management system having a capability to evaluate patient kidney function, the system configured to:

receive input defining a patient's medical record including the patient's demographic information, medical condition and diagnosis;

calculate the patient's estimated glomerular filtration rate based on the patient's medical record;

output at least one medical treatment recommendation wherein the recommendation is based on the patient's medical record and estimated glomerular filtration rate; and

calculate and output at least one treatment goal for the patient.

2. The system of claim 1 wherein the at least one treatment goal for the patient comprises at least one of:

a goal blood pressure, a goal lipid level, a goal cholesterol level and a goal hemoglobin A1C level.

3. The system of claim 1 additionally configured to receive input specifying a treatment for the patient.

4. The system of claim 1 additionally configured to output an indication as to whether, based on the patient's medical record, the at least one medical treatment goal has been met.

5. The system of claim 1 wherein a plurality of clinical treatment algorithms are applied to the patient's medical record to generate the at least one treatment recommendation and the at least one patient treatment goal.

6. The system of claim 1 additionally configured to:
receive input specifying a patient's current medication(s);
receive input specifying a new prescription for the patient; and
generate an alert if the prescribed medication may antagonize a medication the patient is currently taking.

7. The system of claim 1 further configured to:
receive input defining a plurality of patient medical records comprising patient demographic information, medical condition, diagnosis and treatment;
receive input defining at least one medical record parameter to extract from the plurality of medical records; and
automatically generate a report containing an aggregate of the at least one medical record parameter extracted from the plurality of medical records.

8. The system of claim 7 further configured to receive input defining a subset of the plurality of patient medical records from which to extract the at least one medical record parameter.

9. The system of claim 1 additionally configured to receive input, for each patient encounter with his or her healthcare provider, defining the patient encounter wherein each defined patient encounter is appended to the patient's medical record.

10. A computer-implemented patient healthcare management method involving the evaluation of patient kidney function, the method comprising:
defining a patient's medical record including the patient's demographic information, medical condition and diagnosis;
calculating the patient's estimated glomerular filtration rate based on the patient's medical record;

automatically generating at least one medical treatment recommendation based on the patient's medical record and estimated glomerular filtration rate; and calculating at least one treatment goal for the patient.

11. The method of claim 10 wherein the at least one treatment goal for the patient comprises at least one of a goal blood pressure level, a goal lipid level, a goal cholesterol level and a goal hemoglobin A1C level.

12. The method of claim 10 further comprising specifying a treatment for the patient.

13. The method of claim 10 further comprising indicating whether, based on the patient's medical record, the at least one patient treatment goal has been met.

14. The method of claim 10 wherein a plurality of clinical treatment algorithms are applied to the patient's medical record to generate the at least one treatment recommendation and the at least one patient treatment goal.

15. The method of claim 10 further comprising:
specifying the patient's current medications;
specifying a new prescription for the patient; and
generating an alert if the prescribed medication may antagonize a medication the patient is currently taking.

16. The method of claim 10 further comprising:
defining a plurality of patient medical records comprising patient demographic information, medical condition, diagnosis and treatment;
defining at least one medical record parameter to extract from the plurality of medical records; and

automatically generating a report containing an aggregate of the at least one medical record parameter extracted from the plurality of medical records.

17. The method of claim 16 further comprising defining a subset of the plurality of patient medical records from which to extract the at least one medical record parameter.

18. The method of claim 10 further comprising defining each patient encounter with his or her healthcare provider wherein the defined patient encounter is appended to the patient's medical record.

19. A computer-based system for interactively managing patient healthcare and evaluating patient kidney function, the system comprising:

a means for defining a patient's medical record;

a means for establishing the patient's estimated glomerular filtration rate based on the patient's medical record;

a means for generating at least one patient treatment recommendation based on the patient's medical record and estimated glomerular filtration rate; and

a means for calculating at least one treatment goal for the patient.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.